IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Conf. No. 4572
Feng Xu	)	Group Art Unit 1632
Serial No: 10/567,940	)	Examiner: Michael C. Wilson
Filed: September 27, 2006	)	Atty. Docket No. PP019817.0003

For: **INACTIVATED HOST CELL DELIVERY OF POLYNUCLEOTIDES ENCODING IMMUNOGENS**

DECLARATION OF DR. FENG XU UNDER 37 C.F.R. § 131

U.S. Patent and Trademark Office
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Alexandria, VA 22314

I, Feng Xu, hereby declare the following:

1. I am named as the sole inventor of the subject matter claimed in application Serial No. 10/567,940. At the time this application was filed, I was an employee of Chiron Corporation.

2. All work described in this declaration was performed in the United States before October 25, 2002.

3. Before October 25, 2002, I demonstrated that immunization of animals directly with killed bacterial cells of *E. coli* and *Shigella flexineri* with plasmid containing DNA encoding an antigen could generate immune responses directed against the antigen encoded by the DNA.

4. Results showing a cellular response (interferon-γ production) in mice after intramuscular immunization with killed recombinant bacterial cells carrying a plasmid containing DNA encoding HIV gag protein are shown in the table below.

Vaccine	Interferon-γ production (pg/10^6 spleen cells)
Killed *E. coli* DH5α (5×10^5 cfu)	96.4
Killed *Shigella* 1207-3 (5×10^5 cfu)	313
Killed *Shigella* 1207-3 (5×10^4 cfu)	175
Saline	0

5. The data in the table were generated as follows. Bacterial cells were heat killed and injected in a 2 x 50 µl volume into the tibialis anterior muscle of each mouse leg. Saline was used as a negative control. Spleen cells were collected after the immunized mice were challenged intra-peritoneally with a recombinant vaccinia virus that expresses HIV gag protein. The collected spleen cells were then stimulated with HIV gag p7 peptide to measure the cells' ability to respond to the immunogen by producing interferon-γ. The data demonstrate that immunization of mice with killed bacterial cells which harbor a plasmid that contains DNA encoding HIV gag causes an immune response directed against the HIV gag

6. All statements I made in this declaration of my own knowledge are true. I believe all statements made on information and belief to be true. I made these statements with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent.

Dated: 10/22/09

Feng Xu, Ph.D.